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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,122	11/09/2001	Paul Stypulkowski	11738.00024	2402

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,122	STYPULKOWSKI, PAUL	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-22, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 23-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the status of copending applications listed in paragraph 02 of the specification must be updated.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6 and 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claim 6 is unclear because the limitation expressed therein does not appear to further limit amended parent claim 1. If the applicant is simply repeating or rewording the same limitations already present in claim 1, then claim 6 is redundant. If the applicant intends for claim 6 to further limit claim 1, then it is unclear how this is a further narrowing since an extension unit distant from the implantable pulse generator relative to the electrode array must necessarily have a first distance between the pulse generator and the extension unit that is greater than a second distance between the extension unit and the electrode array.

The scope of claim 7 is unclear. The claim previously was drawn to an extension unit (i.e., a subcombination of the apparatus), but now it appears that the applicant is attempting to draft the claim such that the scope is drawn to the combination of the extension unit, pulse generator and electrode array. The applicant has, however, not positively recited the pulse generator or the electrode array in the claim body, making the applicant's intent unclear.

Claim 7 is also confusing in that it refers to the output sources of the pulse generator as being configured to simultaneously trigger a plurality of electrodes, while

claim 23 states that an array of programmable switches associated with the extension unit does the simultaneous triggering. Clarification is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-14 and 23-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al. (Pat. No. 4,628,934).

Regarding claim 1, Pohndorf et al. disclose an apparatus comprising an implantable pulse generator (pacer electronics as shown in Fig. 3) having a number of output sources that transmit electrical signals (note feedthroughs 350 or 381 and 382 of Figs. 8 and 9 respectively) to an implantable electrode array having a number of electrodes (31-34, etc. as shown in Fig. 1), wherein the number of electrodes is greater than the number of output sources, and an extension unit (elements 348 or 378 of Figs. 8 and 9) coupled between the implantable pulse generator and the implantable electrode array and configured to electrically connect the output sources to a portion of the electrodes.

The structure recited in claims 2-4 is clearly anticipated.

Regarding claim 5, the examiner considers the electrodes on leads 26 and 28 shown in Fig. 1 to constitute a multi-dimensional array arrangement.

Regarding claims 6, 25 and 44, the distance between the implantable pulse generator and the extension unit as compared to the distance between the extension unit and the electrode array is relative. One could, for example, take the highly flexible electrode lead and bend it so that the tip of the lead touches near the extension unit, making the distance between the electrode array and the extension unit less than the distance between the extension unit and the pulse generator. Furthermore, the reference to a distance between a first and second landmark as being greater than a

distance between a second and a third landmark can be easily met when the recitation is given its broadest reasonable interpretation. One can take, for instance, a diameter of the lead between the extension unit and electrode array (or any other arbitrary measurement) to be a distance between the unit and the array, and compare this to a distance as measured from the pulse generator to the extension unit and say that the distance represented by the diameter of the lead is less than the distance represented by the second measurement. Furthermore, if one defines the pulse generator as the actual circuit that generates pulses from within the casing of the pacer, and one defines the extension unit as comprising the switching array in combination with the lead body upon which the electrode array resides, then clearly an extension unit separated from the pulse generator by a header/neck 38 (see Fig. 1) would read on claim 6.

Claims 7 and 8 are clearly anticipated. See the "Response to Arguments" section below for further comment. Parallel comments apply to claims 23 and 26.

Regarding claim 9, Pohndorf et al. teach that the switches in the programmable array may be bistable magnetic reed switches in col. 10, lines 12-24. Such relay switches are considered to retain their switching state after power has been removed. The devices are in microcircuit form as per col. 9, lines 53-68.

Regarding claims 10-12 and claims with similar limitations, the examiner considers the electrical paths containing the zener diodes shown in Figs. 3 and 3A to constitute an array of wave shaping circuits, with the diodes inherently shaping the amplitude and frequency of signals received on the output sources in order to attenuate high energy pulses and prevent damage to circuitry.

Concerning claims 13 and 14, the examiner considers any magnetically activated switch to be mechanically and magnetically adjustable. The term "adjustable" merely means capable of adjustment.

Claim 23 is clearly anticipated. See the "Response to Arguments" section below for further comment.

Regarding claim 24, note col. 10, lines 25-40 where the function of sensing is discussed.

Claims 26 and 27 are clearly anticipated. See the "Response to Arguments" section below for further related comment.

Regarding claims 28 and 33, note the rejection of claim 9 above.

Regarding claims 38 and 39, note the rejection of like claims 13 and 14 above.

Claim 40 is clearly anticipated.

Regarding claim 41, note the rejection of like claim 24 above.

Claim 42 is clearly anticipated.

Regarding claim 43, note the rejection of like claim 5 above.

Response to Arguments

6. Applicant's arguments filed December 9, 2004 have been fully considered but they are not persuasive. The applicant argues that the presently amended claims are not anticipated by the Pohndorf et al. reference (the reference referred to by the applicant as "Pohnfort") because (1) Pohndorf et al. do not disclose an extension unit distant from the implantable pulse generator relative to the electrode array, and (2) Pohndorf et al. do not disclose output sources configured to simultaneously trigger a plurality of electrodes.

Regarding the matter of the first point, the examiner considers the extension unit to include the lead bodies upon which the electrodes reside. Given the fact that the extension unit plugs into the header, that the header is spaced from the pulse generator residing within the housing 36, and that the electrode array is contained on the extension unit, one can clearly see that the extension unit is distant from the implantable pulse generator relative to the electrode array.

Regarding the matter of the second point, the applicant points to col. 11, lines 14-16 of the Pohndorf et al. reference in an apparent effort to show that Pohndorf et al. do not disclose the use of output sources configured to simultaneously trigger a plurality of electrodes. The applicant goes on to state that simultaneous triggering of the electrodes in the prior art reference would presumably lead to cardiac injury. The examiner counters that col. 11, lines 14-16 only address one embodiment of the Pohndorf et al. invention. Prior to this recitation, Pohndorf et al. state that tandem

switching is possible with the embodiment shown in Fig. 9. Such switching results in a “two out of four” selection of electrodes (see col. 10, lines 47-66). Pohndorf et al. further teach that bipolar configurations (i.e., two electrodes) may be employed in the practice of the invention (note col. 6, lines 19-22). It is unclear why such arrangements would result in cardiac injury since bipolar pacing and/or sensing has been practiced for many years in the cardiac treatment arts without adverse effect.

Furthermore, regarding claim 7, since the applicant hasn't positively recited the pulse generator with output sources, a recitation attempting to limit a non-element of the invention (i.e., the recitation regarding the output sources configured to simultaneously trigger a plurality of electrodes), will be considered insufficient to saliently distinguish over the apparatus of the Pohndorf et al. reference. The applicant is merely setting forth an extension unit *for use with* an implantable pulse generator with a number of output sources configured to simultaneously trigger a plurality of electrodes. In any event, the examiner considers the output sources of the Pohndorf et al. invention to be configured to simultaneously trigger a plurality of electrodes simply dependent upon the arrangement of the switching array lying between the output sources and the electrode array.

Regarding claim 23, the Pohndorf et al. apparatus is capable of selective sensing as discussed in col. 10, lines 34-40. It is unclear how cardiac damage would occur by simply sensing with two simultaneously triggered electrodes in a bipolar arrangement or in a dual chamber setting. Simultaneously triggering a plurality of electrodes to sense cardiac signals is old and well-known (again note the above comments regarding Pohndorf's use of bipolar arrangements).

Related comments to those made above apply to claim 26 as well.

In summary, lacking any substantive amendment to the claims, the rejections must stand.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
February 23, 2005



KENNEDY SCHAETZLE
PRIMARY EXAMINER